REMARKS

Entry of this Amendment is proper under 37 C.F.R. 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; and does not raise any new issue requiring further search and/or consideration because the amendments amplify issues previously discussed throughout prosecution. The amendment places the application in better form for an appeal should an appeal be necessary.

The Office Action Summary indicates that claims 1-5, 9, 11-15, 19, 21, 30, 31, 34, 36 and 55-57 are pending in the application. Actually, claims 1-5, 9, 11-15, 19, 21, 30, 31, 34, 36 and 55-66 are pending. Claims 58-66 were added in the Amendment and Reply filed August 25, 2004, to which the present Office Action responds.

The Office Action Summary indicates that claims 1-5, 9, 11-15, 19, 21, 30, 31, 34, 36 are allowed and that 55-57 are stand rejected. Claims 58-66 not having been rejected, it is understood that these claims are allowed for at least the reasons set forth in the Office Action.

By the present amendment, claims 55-57 are amended to recite injectable antiviral compositions and claims 67-69 are added to recite the composition of claims 55-57, as formerly presented, in the form of an oral composition. The amendments to claims 55-57, and new claims 67-69, are supported in the disclosure at least at page 26, line 19 to page 28, line 9, and page 28, line 15 through page 29, line 5, wherein the skilled reader is taught excipients used in the art for preparing injectable or orally administered compositions.

No new matter is introduced by the present amendments. Applicants reserve the right to file a continuation or divisional application directed to any subject matter that may have been canceled by the present amendments.

Rejection under 35 U.S.C. § 102(b)

Claims 55-57 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,215,991 to Burke. The rejection is respectfully traversed. The composition taught and claimed by Burke is distinct from the presently claimed compositions for a number of reasons.

The Office asserts that Burke teaches a pharmaceutical composition comprising N,N-hexamethylene amiloride, or N,N-dimethylene amiloride. The Office has asserted that it is well settled that the "intended use" of a composition does not further limit claims drawn to a composition. However, in the present case, one skilled in the art would recognize that the formulation of the composition taught by Burke is necessarily distinct from the composition that is presently claimed, at least because one of skill in the art would recognize that pharmaceutically acceptable ophthalmic formulations are made differently from injectable formulations and formulations for oral administration. In this case, the mode of use and intended result are sufficiently distinct as to render the formulation of the claimed composition distinct. Moreover, there is no teaching in Burke that would lead one to make the presently claimed compositions.

To be precise, the composition taught and claimed by Burke et al. is limited to an ophthalmic preparation, as taught in the specification at column 2, line 38 through column 7, line 22, and as defined in claim 7 as "An ophthalmically acceptable composition for lowering intraocular pressure (IOP) comprising an effective, IOP lowering amount of alpha$_2$ agonist and a potentiating amount of amiloride or its analogs." By the present amendment, claims 55-57 are amended to recite injectable antiviral compositions and claims 67-69 are added to recite the composition of claims 55-57, as formerly presented, in the form of an oral

composition. Pharmaceutical formulations for ophthalmic application are not the same as, and would not be confused with, injectable or oral formulations.

Moreover, the feature of antiviral properties recited in claims 55-57 and 67-69 is not an inherent characteristic of Burke's composition. Burkes compositions include amiloride, which does not possess antiviral properties, and amiloride analogues that do not possess antiviral properties.

Further, Burke does not teach or suggest formulating a composition that comprises an amount of HMA or DMA effective for use as an antiviral as recited in claims 55-57 and 67-69. Rather, Burke teaches formulating an ophthalmically acceptable composition that comprises only an amount of amiloride capable of potentiating an IOP lowering amount of alpha$_2$ agonist. One skilled in the art would recognize that such a composition would be unsuitable for clinical use as an antiviral medicament and therefore distinct from the presently claimed composition. It is well accepted that an antiviral medicament would not be administered ophthalmically in order to successfully achieve a systemic antiviral effect. To provide efficacy, it is well accepted that antivirals must be administered either parenterally or orally such that effective blood levels of the active substances are achieved and maintained during the treatment period.

At page 26, line 19 to page 28, line 9, and page 28, line 15 through page 29, line 5 of the specification the skilled reader is taught well known excipients used in the art for preparing injectable or orally administered compositions. Although the specification teaches a topically administered form of the active compounds at page 28, lines 11 to 13, it would be abundantly clear to a person skilled in the art of treating HIV infection that topical application of the active compounds would not provide sufficient and consistent levels of the active substance to achieve a systemic antiviral effect.

Therefore, Applicants respectfully submit, that the injectable antiviral composition of amended claim 55, and the orally administered antiviral composition of new claim 67 are unlike the ophthalmically acceptable composition taught and claimed by Burke et al. Burke's ophthalmically acceptable composition would not be utilized as an antiviral medicament. Moreover, one skilled in the art would recognize that an opthalmically acceptable composition is different from injectable or oral compositions. For at least the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claims 55-57 and an indication that all pending claims are allowable..

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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